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10/734,274	12/15/2003	Karel Hero Mulder	2005-1021	1503

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EXAMINER

NGUYEN, HUONG Q

ART UNIT PAPER NUMBER

3736

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/734,274

Applicant(s)

MULDER, KAREL HERO

Examiner

Helen Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☒ Claim(s) 1-2, 6-9, 16-18, 20, 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/8/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 10734274, filed on 3/15/2004.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 3/8/2004 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.
3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered. This is directed toward the Netherlands patent NL-A-1015080 listed on p.1 of the specification.

Drawings

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: (a) element number 15 on p.7 line 10; (b) element number 37 on p.8 line 9, both disclosed in the specification.

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Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: (a) element numbers 13 and 21 shown in Figures 2 and 3; (b) element number 22 shown in Figure 2.

Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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6. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the second indicator means of **Claim 5**, the urine indicator means of **Claims 16-18**, and the flow indicator means and time duration indicator means embodied as separate measuring devices between the two foil sheets of **Claims 11, 22** respectively must be clearly shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

7. The disclosure is objected to because of the following informalities:
- (a) Side channels 71..77 disclosed on p.7 line 30 and p.8 line 7-8, 13, 17, 24 should be changed to 71-77.
 - (b) Channels 71..72 disclosed on p.8 line 13 should be changed to 71-72.
 - (c) Reference character “5” has been used to designate both “receiving member” and “disposable article” (p.9 line 30) in the specification. Similarly, reference character “7” has been used to designate both “flow indicator means” and “measuring device” (p.8 line 1, p.9 line 12) in the specification.
 - (d) Collecting device 9 disclosed on p.9 line 5 should be designated as element number 8, as previously presented.
- Appropriate correction is required.

Claim Objections

8. **Claims 1-2, 6-9, 16, 18, 20** are objected to for usage of the phrase “at least” which renders said claims indefinite. Language comprising of “at least” makes it unclear whether the particulars are claimed or not.
9. **Claim 17** is objected to for using the phrase “in particular” which renders said claim indefinite because it is not clear whether the instant case is claimed or not.
10. **Claim 22** is objected to because it refers back to the incorrect claim. **Claim 22** seeks to disclose the limitation of a separate device between two foil sheets. However, **Claim 22** states

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dependency back to **Claim 19**, which does not mention said foil sheets. Appropriate correction is required.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. **Claims 11 and 22** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the instant case, both claims refer to means comprising a separate measuring device enclosed between the two foil sheets. After reading p.4 line 7-10 and p.10 line 20-22 of the specification, it is still unclear how the above-mentioned means are formed separate from the foil sheets. It is also noted that the particulars of said claims have not been clearly shown in the submitted drawings, objected to above in ¶6.

13. **Claim 5** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, it is not clear what is meant by “second indicator means,” solely disclosed on p.3 line 7 of the specification. Is the indicator the same or different than the “volume indicator means” disclosed in Claim 4? For the purposes of examination, it is assumed that said second indicator means is the same as said volume indicator means.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. **Claims 1-8 and 19-21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Dye (US Pat No. 3831446) in view of Bortle (US Pat No. 4296502). In regards to **Claim 1**, Dye discloses a urological instrument (20) comprising: (a) a receiving member, referred to as “funnel-shaped member” (44); (b) a urine guide, referred to as “lower depending portion” (47); (c) a flow indicator means, referred to as “compartment” (38), all best seen in Figures 1-2. Dye discloses said receiving member in open liquid communication with said urine guide (Col.3, line 50-53) and an inlet (58) of said flow indicator means (Col.3, line 31-33) for assessing a magnitude of urine flow, best seen in Figure 2. Dye discloses the flow rate of urine calculated by dividing the value of total volume discharge by time period of discharge, wherein both are calculated at least in part by the amount of liquid that flows into said flow indicator means (38), thus constituting said compartment (38) as flow indicator means (Col.5, line 51-55). It is noted that the aforementioned elements have been defined as such from the explanation available in the specification, as best understood by the examiner.

16. Dye also discloses said receiving member open on at least one side by “inlet port” (45) and comprising a cavity, referred to as “tapered portion” (46), for receiving urine flow, shown in Figure 1 (Col.3, line 37-39). However, Dye does not disclose the receiving member with a first compact storage state and a second expanded ready-to-use state. Bortle discloses a urine conduit

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comprising a receiving member, referred to as “second portion” (22) that is funnel-shaped, in a storage state, referred to as “packed condition,” and adapted to be brought manually from storage state to ready-to-use state for compactness and ease of carrying and disposal, as shown in Figures 2-4 (Col.3, line 4-9, 35-42, 55-58).

17. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the receiving member (44) of Dye to have a first compact storage state and a second expanded read-to-use state, as taught by Bortle, wherein said receiving member is designed and adapted to be brought manually from the first to second state, to enable the urological instrument to be more compact, allowing convenience of carrying and disposal.

18. In regards to **Claim 2**, Dye discloses said instrument (20) provided with a collecting device, referred to as “container” (24), in open communication with an outlet (42) of said flow indicator means (38) (Col.3, line 11-13), wherein said collecting device is provided with a closing member, referred to as “valve means” (64), normally in the closed position (Col.5, line 12-15, 34-38). However, Dye does not disclose the collecting device expandable from a relatively compact storage state to an expanded position of use.

19. Bortle discloses a urine conduit in a packed condition and adapted to be brought manually from packed condition to ready-to-use state for compactness and ease of carrying and disposal, as shown in Figures 2-4 (Col.3, line 4-9, 35-42, 55-58). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the collecting device (24) of Dye to have a compact storage state and an expanded position of use, as taught by Bortle, to enable the urological instrument to be more compact, allowing convenience of carrying and disposal, wherein said collecting device also comprises a “collection bag” (24),

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which is inherently capable of expansion from a compact state due to its flexible nature, as would be obvious to one of ordinary skill in the art (Col.6, line 12-13).

20. In regards to **Claim 3**, Dye discloses the collecting device comprising a collecting bag, referred to as “collection bag” (24) (Col.6, line 12-13). In regards to **Claim 4**, Dye discloses said collecting device provided with volume indicator means for a urine volume received therein, referred to as “graduated indicia” (74) (Col.5, line 45-47).

21. In regards to **Claim 5**, Dye discloses a collecting bag (24) provided with a closing member (64) as described above normally in the closed position, said collecting bag connected to said urine guide (47) on an end opposite said receiving member (44), wherein the collecting bag is provided with second indicator means, referred to as “graduated indicia” (74), for the quantity of urine flow, wherein second indicator means is assumed by examiner to be synonymous with volume indicator means, as stated in ¶13 (Col.5, line 45-47).

22. In regards to **Claims 6-8**, Dye discloses a urological instrument substantially mutually in line in the ready-to-use state but does not disclose the instrument embodied as disposable, formed substantially from flexible material and folded at least in the storage state, wherein in said storage state one or more components of the instrument lie at least substantially folded onto each other. Bortle discloses a urine conduit formed from flexible and deformable material, wherein the instrument is folded at least in the storage state, referred to as “packed condition,” for compactness and ease of carrying and disposal, best seen in Figures 2-4 (Col.3, line 35-42). Due to the nature of “packing” for compactness, any instrument comprising more than one component is inherently folded so that one or more of said components of the instrument lie at least substantially folded onto each other, also clearly shown in Figures 2-4 (Col.3, line 35-42).

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23. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to embody the urological instrument (20) of Dye as a disposable article formed from flexible material capable of being folded at least in the storage state, as taught by Bortle, wherein in said storage state one or more components of the instrument lie at least substantially folded onto each other such that at least one of the receiving member (44) and the collecting device (24) covers the urine guide (47) on one side of the flow indicator means (38), to enable the urological instrument to be more compact, allowing convenience of carrying and disposal.

24. In regards to **Claim 19**, Dye discloses time duration indicator means, referred to as “indicia” (62), for determining a time duration of the urine flow (Col.5, line 2-7). In regards to **Claim 20**, Dye discloses said time duration indicator means comprising a reservoir, referred to as “container” (24), which at least during use is in open communication via a defined passage opening, referred to as “chamber” (34), with the urine flow (Col.4, line 42-52), wherein said reservoir is provided with volume indicator means, referred to as “graduated indicia” (74), for a urine volume received therein (Col.5, line 43-47). In regards to **Claim 21**, Dye discloses said passage opening (34) situated at least close to an inlet (58) of said flow indicator means (38), as seen in Figure 2 (Col.3, line 31-33).

25. **Claims 9-11 and 22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Dye in view of in view of Bortle, further in view of McWhorter (US Pat No. 3831453), further in view of Persson (US Pat No. 3928875). Dye as modified by Bortle discloses a urological instrument formed from flexible material, as explained in the above rejection of Claim 6.

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and Bortle do not disclose the flexible material comprising two foil sheets hermetically to each other on a mutual contact surface, at least partially forming one or more components of said device, wherein said components include the receiving member, the urine guide, the flow indicator means, and the collecting device.

26. McWhorter discloses a urological device formed from two flexible plastic sheets closed by heat, thus constituting a hermetic seal, forming one or more components of the device, in the instant case, a collection bag, referred to as "bag" (Col.1, line 51-61), for more accurate measurement of urine output (Col.1, line 22-23). However, McWhorter does not disclose the two flexible sheets as foil. Persson discloses a urine collector formed of flexible foil material for cheap manufacture and thus, disposability (Col.1, line 9-13).

27. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the urological device of Dye as modified by Bortle, using two sheets hermetically forming one or more components of said device, as taught by McWhorter, wherein said sheets are foil sheets, as taught by Persson, to effectively manufacture an accurate device while keeping costs cheap for economic disposal. As integral manufacture of the instrument components (such as the receiving member, urine guide, collecting device) is possible, it would then also be obvious to manufacture specific components of said urological device as separate from said foil sheets, for example, flow indicator means or time duration indicator means, for reasons such as better precision, as such methods of manufacture are obvious in view of McWhorter and known to those skilled in the art.

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28. **Claim 12** is rejected under 35 U.S.C. 103(a) as being unpatentable over Dye in view of Bortle, further in view of Griffiths (US Pat No. 2856932). Dye discloses a urological instrument (20) but does not disclose said device provided with an irreparable breakable seal. Griffiths discloses a urethral catheter and bag maintained in a storage state, wherein the device is opened from a storage state to a ready-to-use state by breaking an irreparable breakable seal, referred to as “flag” (36), for ease of use and disposal, best seen in Figures 2, 3, 5 (Col.3, line 56-62, 71-74). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a similar irreparable breakable seal as taught by Griffiths into the urological instrument disclosed by Dye as modified by Bortle, for holding said instrument in the storage state, wherein the breaking of said seal brings the instrument into ready-to-use state, as an effective method to maintain device sterility and convenience of use.

29. **Claim 13** is rejected under 35 U.S.C. 103(a) as being unpatentable over Dye in view of Bortle, further in view of Oxley (US Pat No. 5423792). Dye discloses a urological instrument (20) but does not disclose recording means arranged on an outer side for manual recording of indicator values determined with said device. Oxley discloses a fluid collection container having a recording means or identification element, in particular, a “writeable area” (42), for manual recording of information (Col.6, line 62-66). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a similar recording means as taught by Oxley into the urological device of Dye as modified by Bortle to provide a means to effectively classify and identify said device.

30. **Claims 14-15** are rejected under 35 U.S.C. 103(a) as being unpatentable over Dye in view of Bortle, further in view of Oxley (US Pat No. 5423792), further in view of LeVeen et al (US Pat No. 4532936). Dye as modified by Oxley discloses a urological instrument with a recording means but do not disclose the means as a removable self-adhesive label. LeVeen et al disclose urological data printed on self-adherent paper for ease of information transfer (Col.5, line 8-10). Therefore, it would have been obvious to one of ordinary skill to modify the recording means of Oxley to be a self-adhesive label, as taught by LeVeen et al, and incorporate that into the device of Dye as modified by Bortle, to provide ease of urological information recording and transfer. Similarly, it would have been obvious to arrange such label at a position on said urological device such as at the position of a flow indicator means while leaving a transparent window for display of information.

31. **Claims 16-18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Dye in view of Bortle, further in view of Hiruta et al (US Pat No. 5111539). Dye discloses a urological instrument (20) but does not disclose urine indicator means in the form of a flexible carrier, such as paper, used to determine at least one component of urine composition, wherein said composition comprises glucose, bilirubin, ketones, blood, proteins, urobilinogen, nitrites, leucocytes, and acids. Hiruta et al disclose a urological device comprising urine indicator means, referred to as "urine test paper piece" (6), placed in a urine path to as an effective method to determine at least one component of urine composition such as glucose, urobilinogen, or blood (Col.6, line 26-37). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to improve the urological device of Dye as modified by Bortle,

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to include a urine indicator means in the form of a paper carrier to determine a desired component of urine composition, as taught by Hiruta et al, to provide an effective method of obtaining other essential urological data from a urine sample, enabling said urological instrument to be more complete and useful.

Conclusion

32. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Blaney (US Pat No. 6346097), Cross (US Pat No. 5605161), and Mattsson (US Pat No. 4886509) all disclose devices with urological applications.

33. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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